
(Health Care Agency)

MEDICAL DIRECTIVE: COMIRNATY COVID-19 Vaccine® (Monovalent Pfizer-BioNTech, 30 mcg)

Original Date: _____

Next Review Date: _____

Contact Officer: _____

Order/Delegated Procedure

Administer injectable Comirnaty COVID-19 vaccine , hereinafter referred to as Monovalent Pfizer-BioNTech COVID-19 vaccine (30 mcg).

Recipient Clients

Authorized for use in those 12 years of age and older as a two dose primary series of 30mcg each.²

Authorized in those 12 years of age and older as a booster dose of 30 mcg each.²

In alignment with NACI's recommendation, the Ministry of Health has made a preferential recommendation for the use of Pfizer-BioNTech COVID-19 vaccine for individuals 5-29 years of age. This recommendation stems from an observed increase in the number of reports of myocarditis/pericarditis following vaccination with Moderna relative to Pfizer-BioNTech in adolescents and young adults, particularly among males, in Ontario, Canada, and internationally.²

NACI recommends that the authorized dose of a bivalent Omicron-containing mRNA COVID-19 vaccine are the preferred booster products for the authorized age groups (≥ 12 years of age). For individuals in authorized age groups who are not able or willing to receive a bivalent Omicron-containing mRNA COVID-19 vaccine, an original mRNA COVID-19 vaccine may be offered.³

Authorized Implementers

Health care providers _____ are described as: _____
(Agency Name) (Agency Health Care Provider)

who have completed the required orientation, including a review of related policies, educations training at clinics and observation by the _____.
(Agency Designate)

Vaccine Administration Error and Deviations

Any deviations in this medical directive shall be documented by the Authorized Implementer and the _____ after informing the Contact Officer or designate
(Agency Designate)

by phone. The Contact Officer will notify the Authorizing Physician*

*Note: Common errors and deviations in COVID-19 vaccine administration that are described in the Government of Canada [Planning guidance for immunization clinics for COVID-19 vaccines: Managing vaccine administration errors or deviations](#) (Last Date Modified: November 17, 2022 or as current)⁸ do not require notification of the Authorizing Physician, except in all cases where a vaccine is administered to a recipient in whom the vaccine is contraindicated or not indicated. For example, vaccine administered to an individual under the age for which the vaccine is authorized in Canada must be reported to the Authorizing Physician, whereas vaccination with a partial dose of vaccine in error to a person for whom the full vaccine dose is indicated that is addressed according to the Provincial guidance does NOT require notification of the Authorizing Physician.

Indications

- Monovalent Pfizer-BioNTech COVID-19 vaccine (30 mcg) is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS- CoV-2)¹.

Contraindications

Clients are **NOT ELIGIBLE** for Monovalent Pfizer-BioNTech COVID-19 vaccine (30 mcg) under this medical directive if there is a risk of serious adverse reaction identified during their health assessment:

- A history of anaphylactic reaction to a previous dose of the Monovalent Pfizer-BioNTech COVID-19 vaccine (30 mcg).¹
- A history of proven immediate or anaphylactic hypersensitivity to any component of the Monovalent Pfizer-BioNTech COVID-19 vaccine (30 mcg) or its packaging.¹ Components of the Monovalent Pfizer-BioNTech COVID-19 vaccine (30 mcg) are listed in Appendix A.

The vaccine should not be administered in a general vaccine clinic. The client must seek evaluation by an appropriate physician or Nurse Practitioner (NP). Such an assessment is required to assess the method for possible (re)administration of a COVID-19 vaccine.⁹

Documentation after discussion with the health care provider is to be provided at the clinic including a vaccination care plan and **parameters the clinic should meet to provide safe vaccine administration.**⁹

Precautions

- Individuals 6 months and older, may receive a COVID-19 vaccine simultaneously with (i.e., same day), or at any time before or after non-COVID-19 vaccines (including live and non-live vaccines). For further information and recommendations surrounding co-administration of COVID-19 vaccines with other non-COVID-19 vaccines refer to the Ministry of Health COVID-19 Vaccine Guidance (Version 4.0, or as current).⁴
- As a precautionary measure until more information is available, further doses of mRNA COVID-19 vaccines should be deferred among individuals who have experienced myocarditis (with or without pericarditis) within the 6 weeks following a previous dose of an mRNA COVID-19 vaccine in most circumstances. This includes any person who had an abnormal cardiac investigation including ECG, elevated troponins, echocardiogram or cardiac MRI after a dose of an mRNA COVID-19 vaccine. For further information on subsequent immunization in individuals who experienced myocarditis and/or pericarditis within 6 weeks of receiving an mRNA COVID-19 vaccine refer to the Government of Canada COVID-19 Vaccine: Canadian Immunization Guide (Last Date Modified: December 22, 2022 or as current).²
- Individuals should seek medical attention if they develop symptoms of Bell's palsy following receipt of mRNA COVID-19 vaccines. Very rare cases of Bell's palsy (typically temporary weakness or paralysis on one side of the face) have been reported following vaccination with COVID-19 mRNA vaccines (Pfizer-BioNTech or Moderna) in Canada and internationally among individuals aged 12 years and older. Refer to the Ministry of Health COVID-19 Vaccine Guidance (Version 4.0, or as current) guidance document for further information and possible symptoms.⁴
- Individuals with a proven severe allergic reaction (e.g. anaphylaxis) to injectable therapy not related to a component of the COVID-19 vaccines (e.g. other intramuscular, intravenous or subcutaneous vaccines or therapies) may be routinely vaccinated with COVID-19 vaccines with a 30 minute post-vaccination observation period.²
- Individuals with a suspected but unproven allergy to a vaccine component (e.g. PEG) may be routinely vaccinated with COVID-19 vaccines with a 30 minute post-vaccination observation period.²
- Individuals with a history of allergy not related to a component of authorized COVID-19 vaccines or other injectable therapy (e.g. foods, oral drugs, insect venom or environmental allergens) can receive COVID-19 vaccines without any special precautions. Individuals should be observed for a minimum of 15 minutes following vaccination. ²
- In individuals with bleeding disorders, the condition should be managed prior to immunization to minimize the risk of bleeding. Individuals receiving long-term anticoagulation are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized without discontinuation of their

anticoagulation therapy.²

- Symptoms, either current or displayed recently, of chest pain or shortness of breath:
 - Vaccine should not be offered to persons displaying current or recent history of chest pain or shortness of breath.
 - Persons displaying current or recent history of chest pain or shortness of breath should consult with a health care provider prior to vaccination and/or if symptoms are severe, should be directed to the emergency department or instructed to call 911.⁴
- Individuals with a history of fainting/dizziness or fear of injections/needle can safely receive the COVID-19 vaccine. Considerations may include:
 - Immunize while seated to reduce injuries due to fainting.
 - If considered high-risk, immunize while laying down.
 - These individuals may bring a support person.⁴
- Vaccination of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness. However, vaccination should be deferred in symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, or those with respiratory symptoms, to minimize the risk of COVID-19 transmission at an immunization clinic/venue. If any person is identified with symptoms on arrival at the venue, they should not be immunized and should be instructed to seek medical and public health advice and follow current local public health measures.²
- As a precautionary measure and in light of the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses, people should wait until all symptoms of an acute illness are resolved before vaccinating with a COVID-19 vaccine.²
- The Ontario Ministry of Health, in alignment with NACI, continues to recommend that COVID-19 vaccines should be offered to individuals with previous SARS-CoV-2 infection without contraindications. For additional information and suggested intervals between previous SARS-CoV-2 infection and COVID-19 vaccination please refer to the Ministry of Health [COVID-19 Vaccine Guidance](#) document (Version 4.0 or as current).⁴
- Clients currently experiencing moderate/severe, acute illness should have their vaccination postponed until the illness has resolved.²

Additional Special Considerations and Booster Dose Eligibility

- It is recommended that COVID-19 vaccines should not be given concurrently with anti-SARS-CoV-2 monoclonal antibodies. Administration of these products concurrently may result in decreased effectiveness of the COVID-19 vaccine and/or anti-SARS-CoV-2 monoclonal antibodies.²
- After reviewing the published literature and evidence sought from manufacturers of COVID-19 vaccines, NACI approved changes to the guidance to indicate that

vaccination with COVID-19 vaccines may take place at any time before, after or at the same visit as the TST or IGRA test.²

- For the most current information related to specific populations (e.g. [Persons with an autoimmune condition](#), [Immunocompromised persons](#), [Travellers](#), [Persons new to Canada](#)), please refer to the Government of Canada COVID-19 vaccine: Canadian Immunization Guide (last date modified: 2022-12-09 or as current).² For guidance and booster dose recommendations for pregnant and breastfeeding individuals refer to the Ministry of Health [COVID-19 Vaccine Guidance](#) document (Version 4.0 or as current).⁴

Obtaining Consent

Appropriate informed consent must be obtained as per the *Guidelines for Implementing the Order/Delegated Procedure* and the client must NOT have any contraindications.

Guidelines for Implementing the Order/Delegated Procedure

Nurses and nursing students are expected to prepare and administer vaccine(s) to clients in a safe, effective, and ethical manner, and to be accountable for their actions. Nurses and nursing students are expected to meet the CNO's [Medication Practice Standard](#) by performing all the administration and verification steps to minimize the chance of error.⁷

Nurses and nursing students are expected to consult with their _____
(Agency Designate)

if unable to perform their nursing duties in a safe and effective manner.

Responsibilities of the nurse and nursing student who implement the intervention include the following:

- Clarify that informed consent has been obtained
- Assess the client to determine whether the specific client conditions and any situational circumstances identified in the directive have been met
- Know the risks to the client of implementing the Order/Delegated Procedure
- Possess the knowledge, skills and judgement required to implement the directive safely
- Know the predictability of the outcomes of the intervention
- Determine whether management of the possible outcomes is within their practice; if so whether they are competent to provide management of outcomes and if not, whether the appropriate resources are available to assist as required.

Administration of vaccine must be in accordance with the manufacturers' product information monographs and the NACI's Recommendations on the use of COVID-19 vaccine(s).²

At all clinics where immunizing agents are administered, the _____
(Agency Designate)

will be available for consultation.

Informed Consent

To obtain informed consent, the nurse and/or nursing student must ensure:

- The purpose of the immunization, desired outcome, risks, and benefits are reviewed.
- The client has read and understood the information on the appropriate COVID-19 Vaccine Information Sheet(s). If the client cannot read the sheet, it should be read or explained to them. The nurse must ensure the client has no contraindications to the vaccine as specified in the "Contraindications" section of this Medical Directive and query regarding current health (e.g., immunosuppression) and precautions.
- The client has had the opportunity to ask questions about the vaccine and had these questions answered to their satisfaction.
- The client has provided informed written or verbal consent to the nurse administering vaccine.

Capacity to provide consent

A client can give consent if they understand the information that is being presented to them and appreciate the foreseeable consequences of their decision or lack of decision.

When in doubt about informed consent or a medical condition of the client, do not administer the vaccine and consult with the _____.

(Agency Designate)

Monovalent Pfizer-BioNTech COVID-19 vaccine (30 mcg)

Dose and Schedule for Monovalent Pfizer-BioNTech COVID-19 vaccine (30 mcg) ^{1,4}:

Age Range	Vaccination	Dose	Presentation	Dose Volume	Intervals ²
≥12 years of age	Two dose Primary Series	30mcg	Grey Cap Grey Label/Border	0.3 mL	<ul style="list-style-type: none">• <u>Minimal</u>: 19 days• <u>Authorized</u>: 21 days• <u>Recommended</u>: 8 weeks

COVID-19 Booster Dose Recommendations

For population-specific booster dose recommendations including dosing, intervals and recommended vaccine, refer to the Ministry of Health document [COVID-19 Vaccine Guidance](#) document (Version 4.0, or as current).⁴

3-Dose Primary Series for Moderately to Severely Immunocompromised

For 3-dose primary series, refer to the Ministry of Health document [COVID-19 Vaccine Guidance](#) document (Version 4.0, or as current).⁴ For additional information on the immunization of immunocompromised persons, the Government of Canada COVID-19 vaccine: Canadian Immunization Guide (Last Date Modified 2022-12-09 or as current).²

Preparation and Administration of the Monovalent Pfizer-BioNTech COVID-19 vaccine (30 mcg)

For the injection technique, follow the *Injection Technique Policy and Procedure* of _____ in conjunction with the following resources below.
(Agency Name)

For basic information on vaccine administration, refer to the Ministry of Health document [COVID-19 Vaccine Guidance](#) document (Version 4.0, or as current).⁴

For step-by-step directions for administration, refer to the [Product Monograph – Pfizer-BioNTech COVID-19 Vaccine](#) (Date of Revision: September 9, 2022 or as current).¹

Storage Requirements and Additional Doses from Vaccine Vials

For detailed information on storage requirements, refer to the Ministry of [Health General COVID-19: Vaccine Storage and Handling Guidance](#) document (Version 1.0 July 22, 2022, or as current) document.⁹

Documentation and Communication

Documentation of administered doses into the COVax database post vaccination should be followed in conjunction with the _____ documentation procedure
(Agency Name)

and the *College of Nurses of Ontario's Documentation Practice Standard*.⁶

Adverse Reactions

The following adverse events have been reported as being common, very common or uncommon after either dose of the Comirnaty COVID-19 vaccine²:

Very common: may affect more than 1 in 10 people

- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- diarrhea

Common: may affect more than 1 in 100 and up to 1 in 10 people

- injection site redness
- injection site swelling
- nausea
- vomiting

Uncommon: may affect up to 1 in 100 people

- enlarged lymph nodes
- feeling unwell
- arm pain¹
- feeling weak or lack of energy/sleepy
- decreased appetite
- excessive sweating
- night sweats¹

Post Vaccination Observation

Recommendations for the post-vaccination observation period for other vaccines during the pandemic, such as for influenza vaccine, should continue to be followed. Therefore, advise clients to remain in the post-vaccination waiting area for the length of time as recommended in the Ministry of Health [COVID-19 Vaccine Guidance](#) document (Version 4.0 or as current).⁴

Serious Adverse Reactions

In situations of suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, the _____ shall be consulted prior
(Agency Designate)

to vaccination, to determine the appropriateness of the vaccination, the option of vaccination in a controlled setting and/or the use of an extended post-vaccination observation period.

As per s.38 of the *Health Protection and Promotion Act*, those administering vaccines should ensure that the vaccine recipients are advised to immediately call their doctor/nurse practitioner or go to the nearest hospital emergency department if they develop a reaction that could be related to the vaccine.⁵ Specifically, the client should be monitored for⁴:

- Hives
- Swelling of the mouth and throat
- Altered level of consciousness/serious drowsiness
- Trouble breathing, hoarseness or wheezing
- High fever (over 40°C or 104°F)
- Convulsions (seizures)
- Other serious reactions (e.g., "pins and needles" or numbness)

If a reaction as described above occurs while at a _____ clinic,
(Agency Name)

refer to the *Medical Directive for Anaphylaxis Management*.

Adverse events/reactions must be documented and reported to the Renfrew County and District Health Unit as per the _____ procedure on
(Agency Name)

Reporting Adverse Events Following Immunization.

Approving _____(s)/Authorizer(s):
(Agency Designate)

NAME: SIGNATURE:	DATE:
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Appendix A – Components of the Monovalent Pfizer-BioNTech COVID-19 vaccine (30 mcg) and its Packaging

For a comprehensive list of components in the vaccine and packaging, please consult the product leaflet or information contained within the product monograph available through Health Canada's Drug Product Database.¹

Potential non-medicinal ingredients in the vaccine or its container known to cause type 1 hypersensitivity reactions ranging from mild cutaneous reactions to anaphylaxis includes the following (which may not be a complete list):

- polyethylene glycol (PEG)²

The full list of non-medical ingredients is as follows:¹

- ALC-0315 = ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)
- ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide
- 1,2-Distearoyl-sn-glycero-3-phosphocholine
- Cholesterol
- dibasic sodium phosphate dihydrate
- monobasic potassium phosphate
- potassium chloride
- sodium chloride
- Sucrose
- Water for injection

does not contain any preservatives, antibiotics, adjuvants, or human- or animal-derived materials. The glass vials have a stopper which does not contain natural rubber latex.¹

REFERENCES

1. Product Monograph – Pfizer-BioNTech COVID-19 Vaccine (Date of Revision: September 9, 2022 or as current): <https://covid-vaccine.canada.ca/info/pdf/pfizer-biontech-covid-19-vaccine-pm1-en.pdf>
2. Government of Canada COVID-19 vaccine: Canadian Immunization Guide (Last Date Modified: December 22, 2022 or as current): <https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html>
3. NACI's updated guidance on COVID-19 vaccine booster doses in Canada. October 7, 2022: <https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/guidance-covid-19-vaccine-booster-doses.pdf>
4. Ministry of Health COVID-19 Vaccine Guidance, Version 4.0 December 20, 2022: https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/COVID-19_vaccine_administration.pdf
5. Health Protection and Promotion Act: <https://www.ontario.ca/laws/statute/90h07#BK45>
6. College of Nurses of Ontario. Documentation, revised 2008. Toronto, ON: 2019. Available from: http://www.cno.org/globalassets/docs/prac/41001_documentation.pdf
7. College of Nurses of Ontario's *Medication Practice Standard* (Last Updated January 2019 or as current): https://www.cno.org/globalassets/docs/prac/41007_medication.pdf
8. Government of Canada, Planning guidance for immunization clinics for COVID-19 vaccines: Managing vaccine administration errors or deviations. (Last Date Modified: November 17, 2022 or as current): <https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/guidance-documents/quick-reference-guide-covid-19-vaccines/managing-administration-errors-deviations.html>
9. Ministry of Health Document: General COVID-19: Vaccine Storage and Handling Guidance, Version 1 July 22,2022: https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/vaccine_storage_handling_pfizer_moderna.pdf